



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2022-0064; FRL-9460-01-OCSP]

RIN 2070-ZA16

### Hypochlorous Acid; Exemption from the Requirement of a Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to exempt residues of the antimicrobial pesticide ingredient hypochlorous acid from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places. This rulemaking is proposed on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) to address residues identified as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2020-0244 by one of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Anita Pease, Antimicrobials Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

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## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are a pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

### **II. Background**

#### *A. What action is the Agency taking?*

EPA is proposing to establish an exemption from the requirement of a tolerance for residues of the antimicrobial pesticide hypochlorous acid on food-contact surfaces in public eating places. EPA is proposing this exemption to cover residues of hypochlorous acid that may be found in food as a result of the use of these antimicrobials on food-contact surfaces.

As noted in the December 2020 *Hypochlorous Acid Interim Registration Review Decision* (available at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2020-0244), hypochlorous acid is registered for use as a disinfectant on food-contact surfaces in public eating places. As a result of that use, residues of hypochlorous acid may be found in food that comes into contact with treated surfaces.

According to the Agency's 2016 Antimicrobial Use Site Index (<https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-use-site-index>), EPA categorizes that use as an "indirect food use." 40 CFR 158W requires a tolerance or exemption for direct and indirect food uses. Historically, EPA did not require a tolerance or tolerance exemption for the registered uses of hypochlorous acid because the labels required a potable water rinse after application. EPA's scientific assumption had been that if an antimicrobial pesticide use required a potable water rinse on the label, residues of the pesticide would be rinsed away. With no residues available to transfer to foods coming into contact with the treated food surface, the use was considered nonfood; and therefore, no tolerance or tolerance exemption was needed. The presumption that there would be no available residues for transfer to food is no longer supportable because available data now suggest that a potable water rinse may not be 100% efficient in removing residues; therefore, the Agency no longer considers a use to be "nonfood" just because the label requires a potable water rinse. Absent information supporting a conclusion that no residues would be available for transfer to food from the use, a tolerance or tolerance exemption is required. At this time, the Agency has not received any information supporting a conclusion that residues of hypochlorous acid would not be available for transfer to food after application to food surfaces.

*B. What is the Agency's authority for taking this action?*

A “tolerance” represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCFA, 21 U.S.C. 346(a), authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues are considered unsafe and therefore “adulterated” under FFDCFA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce, 21 U.S.C. 331(a).

Section 408(e)(1)(B) of the FFDCFA authorizes EPA to issue an exemption from the requirement of a tolerance on its own initiative. 21 U.S.C. 346a(e)(1)(B). It is under section 408(e) of the FFDCFA that EPA is proposing to establish the exemption in this rulemaking. The standard for establishing an exemption is found in section 408(c)(2)(A) of the FFDCFA and is discussed below. 21 U.S.C. 346a(c)(2)(A).

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCFA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCFA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to take into account, among other things, the considerations set forth in section 408(b)(2)(C) and (D). Specifically, section 408(b)(2)(C) of FFDCFA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants

and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to support the establishment of exemptions from the requirement of a tolerance for residues of hypochlorous acid.

As noted in the *Hypochlorous Acid Interim Decision*, there are tolerances under 40 CFR § 180.940 (b) and (c), which state that solutions containing hypochlorous acid may be applied to dairy-processing equipment, and food-processing equipment and utensils, with the limitation that the end-use concentration of hypochlorous acid does not exceed 200 ppm determined as total available chlorine. Because the current tolerance exemptions do not cover the antimicrobial products registered for use in public eating areas, the Agency is now establishing a tolerance exemption under section 40 CFR § 180.940(a), which would cover all food-contact uses of hypochlorous acid pesticide products in public eating areas not to exceed 200 ppm determined as total available chlorine. EPA’s safety determination for establishing a hypochlorous acid tolerance exemption under section 40 CFR § 180.940(a) is based on chemical similarity to sodium, calcium, and potassium hypochlorites. Hypochlorous acid risk conclusions, including those related to dietary and aggregate exposure, can be bridged to the risk conclusions from the reevaluation of the sodium, calcium, and potassium hypochlorites (see docket EPA-HQ-OPP-2012-0004 at <https://www.regulations.gov>). Because the Agency did not identify any dietary or aggregate risks of concern for the sodium, calcium, and potassium hypochlorites, due to the lack of toxicity of these substances, there are no dietary or aggregate risks of concern for hypochlorous acid due to a lack of toxicity for hypochlorous acid. For further information, the *Hypochlorous Acid Interim Decision* can be found at <https://www.regulations.gov> in docket identification number EPA-HQ-OPP-2020-0244.

Based on the lack of any aggregate risks of concern, EPA concludes that the exemption from the requirement of a tolerance for residues of hypochlorous acid is safe, *i.e.*, there is a

reasonable certainty that no harm will result from aggregate exposures to hypochlorous acid.

#### **IV. Analytical Enforcement Methodology**

An analytical method for residue is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of hypochlorous acid in or on any food commodities. EPA is establishing limitations on the amount of hypochlorous acid that may be used in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. 136 *et seq.* EPA will not register any antimicrobial pesticide formulation applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils that allows for the end-use concentration of the ready to use product to exceed the 200 ppm limit for residues of total available chlorine.

#### **V. Conclusion**

Therefore, EPA is proposing to establish an exemption under 40 CFR § 180.940(a) from the requirement of a tolerance for residues of hypochlorous acid when used in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils not to exceed 200 ppm determined as total available chlorine. Because the existing entries in paragraph (b) and (c) are duplicative of the new exemption in paragraph (a) of section 40 CFR § 180.940, EPA is removing the tolerance exemptions for hypochlorous acid in paragraphs (b) and (c), as unnecessary.

#### **VI. Statutory and Executive Order Reviews**

In this document, EPA is proposing to establish exemptions from the requirement of a tolerance under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this proposed rule has been

exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collection subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations as required by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This proposed rule does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published in the *Federal Register* of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. Furthermore, for the pesticides named in this proposed rule, the Agency knows of no

extraordinary circumstances that exist as to the present proposed rule that would change EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCFA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any "tribal implications" as described in Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000). Executive Order 13175 requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the executive order to include regulations that have "substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes." This proposed rule will not have substantial direct effects on

tribal governments, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 9, 2022.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Amend § 180.940, by:

a. Adding in alphabetical order the pesticide chemical “Hypochlorous Acid” to the table in Table 1 to Paragraph (a).

b. Removing the entry “Hypochlorous Acid” from the table in paragraph (b).

c. Removing the entry “Hypochlorous Acid” from the table in paragraph (c).

The addition reads as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \* \*

(a) \* \* \*

Table 1 to Paragraph (a)

<b>Pesticide Chemical</b>	<b>CAS Reg. No.</b>	<b>Limits</b>
*	*	*
Hypochlorous Acid	7790-92-3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
*	*	*

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